

NOVEL APPROACHES TO ENHANCE ANIMAL STEM CELL RESEARCH

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Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:

National Institutes of Health (NIH)

(<http://www.nih.gov>)

COMPONENTS OF PARTICIPATING ORGANIZATION:

National Center for Research Resources (NCRR)

(<http://www.ncrr.nih.gov/>)

National Cancer Institute (NCI)

(<http://www.nci.nih.gov/>)

National Eye Institute (NEI)

(<http://www.nei.nih.gov/>)

National Heart, Lung and Blood Institute (NHLBI)

(<http://www.nhlbi.nih.gov/>)

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(<http://www.niams.nih.gov/>)

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(<http://www.nibib.nih.gov/>)

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(<http://www.nichd.nih.gov/>)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

(<http://www.niddk.nih.gov/>)

National Institute of Environmental Health Sciences (NIEHS)

(<http://www.niehs.nih.gov/>)

National Institute of Mental Health (NIMH)

(<http://www.nimh.nih.gov/>)

National Institute of Neurological Disorders and Stroke (NINDS)

(<http://www.ninds.nih.gov/>)

National Institute on Aging (NIA)

(<http://www.nia.nih.gov/>)

National Institute on Deafness and Other Communication Disorders (NIDCD)

(<http://www.nidcd.nih.gov/>)

National Institute on Drug Abuse (NIDA)

(<http://www.nida.nih.gov/>)

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THIS PA CONTAINS THE FOLLOWING INFORMATION

- o Purpose of the PA
- o Research Objectives
- o Mechanism(s) of Support
- o Eligible Institutions
- o Individuals Eligible to Become Principal Investigators
- o Where to Send Inquiries
- o Submitting an Application
- o Supplementary Instructions
- o Peer Review Process
- o Review Criteria
- o Award Criteria
- o Required Federal Citations

PURPOSE OF THIS PA

The purpose of this program announcement (PA) is to encourage the submission of applications for research to enhance animal stem cells as model biological systems. Innovative approaches to isolate, characterize and identify totipotent and multipotent stem cells from nonhuman biomedical research animal models, as well as to generate reagents and techniques to characterize and separate those stem cells from other cell types is encouraged. Studies involving human subjects are not allowed under this PA. This PA supersedes [PA-02-147](#) issued earlier by the NCRR.

RESEARCH OBJECTIVES

Embryonic stem cells and other stem cells are valuable biomedical research models for the study of biological and disease processes, and for creation of disease models. In addition, these cells hold promise as model systems for development of therapeutics and for development of replacement tissues through understanding of control of cellular differentiation.

Thus far, embryonic stem cells have been isolated from some biomedically important nonhuman research models. In addition, stem cells with a more restricted potential have been characterized from post-embryonic tissue types. However, research is needed to provide for a full array of totipotent and multipotent stem cells from nonhuman biomedical research animal models, as well as to provide the research tools to identify, characterize, and purify those cells.

This initiative will support the isolation and characterization of embryonic and other multipotent stem cells in a variety of nonhuman animal species.

Examples of research areas appropriate to this announcement include, but are not limited to:

- o Projects to expand the number of nonhuman animal model systems in which embryonic stem cells are available.
- o Projects to identify, isolate, culture and characterize multipotent stem cell populations derived from nonhuman embryonic stem cells.
- o Projects to identify, isolate, culture and characterize multipotent stem cells from post-fetal tissue types.
- o Projects to generate and use panels of markers for stem cell attributes common across species for use in characterization and isolation of stem cells in a range of animal species or tissues.
- o Projects to create universal methods of culture to maintain the undifferentiated state of embryonic or other characterized, multipotential stem cells across nonhuman animal species.

Projects supported by the National Center for Research Resources under this PA are intended to generate research tools, reagents or stem cells of utility to research on a broad range of tissue or cell types and of interest to more than one categorical or disease-oriented Institute or Center of the National Institutes of Health. Projects that will focus on research on tissues or disease processes specific to the mission of an Institute or Center should be directed to the respective Institute or Center.

The research supported under this PA should clearly expand the usefulness of nonhuman animal model systems by generating multipotential stem cells appropriate to those systems and tools that will allow for further research on those stem cells.

MECHANISMS OF SUPPORT

This PA will use the NIH R01 and R21 award mechanisms. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

R21 applications should meet the requirements for this mechanism as recently redefined in PA-03-107, “NIH Exploratory/Developmental Research Grant Award (R21);” <http://grants.nih.gov/grants/guide/pa-files/PA-03-107.html>. In brief, by using the R21 mechanism, the NIH seeks to foster the introduction of novel scientific ideas, model systems, tools, agents, targets, and technologies that have the potential to substantially advance biomedical research. The R21 mechanism is intended to encourage new exploratory and developmental research projects. For example, such projects could assess the feasibility of a novel area of investigation or a new experimental system that has the potential to enhance health-related research. Another example could include the unique and innovative use of an existing methodology to explore a new scientific area.

These studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models or applications that could have major impact on a field of biomedical, behavioral, or clinical research.

Applications for R21 awards should describe projects distinct from those supported through the traditional R01 mechanism. For example, long-term projects, or projects designed to increase knowledge in a well-established area will not be considered for R21 awards. Applications submitted under this mechanism should be exploratory and novel. These studies should break new ground or extend previous discoveries toward new directions or applications.

Applications for R21 awards may request a project period of up to two years with a combined budget for direct costs of up to \$275,000 for the two year period. For example, the applicant may request \$100,000 in the first year and \$175,000 in the second year. The request should be tailored to the needs of the project. Normally, no more than \$200,000 may be requested in any single year.

This PA uses just-in-time concepts. It also uses the modular budgeting as well as the non-modular budgeting formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular budget format. Otherwise follow the instructions for non-modular budget research grant applications. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part2.htm.

ELIGIBLE INSTITUTIONS

You may submit an application if your institution has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal government
- o Domestic or foreign institutions/organizations
- o Faith-based or community-based organizations

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

An application with direct costs greater than \$500,000 in any single year will be expected to address data sharing, as described in NOT-OD-03-032, “Final NIH Statement on Sharing Research Data;” <http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into two areas: scientific/research and financial or grants management issues:

o Direct your questions about scientific/research issues to:

John D. Harding, Ph.D.
Division of Comparative Medicine
National Center for Research Resources
6701 Democracy Boulevard, Room 950, MSC 4874
Bethesda, MD 20892-4874
Telephone: (301) 435-0744
FAX: (301) 480-3819
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Cancer Cell Biology Branch
Division of Cancer Biology
National Cancer Institute
6130 Executive Boulevard, Suite 5000
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Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 10154
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Cellular Basis of Metabolic Diseases Program
National Institute of Diabetes and Digestive and Kidney Diseases
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Jerrold Heindel, Ph.D.
Division of Extramural Research and Training
Cellular, Organ and Systems Pathobiology Branch
National Institute of Environmental Health Sciences
79 T.W. Alexander Drive
4401 Building, 3rd Floor
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Beth-Anne Sieber, Ph.D.
Developmental Neurobiology Program
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Taste and Smell Program
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Rockville, MD 20852
Telephone: (301) 402-3464

FAX: (301) 402-6251
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National Institute on Drug Abuse
6001 Executive Boulevard, Room 4282, MSC 9555
Bethesda, MD 20892-9555
Telephone: (301) 435-1305
FAX: (301) 594-6043
Email: glin@nida.nih.gov

o Direct your questions about financial or grants management matters to:

Ms. Irene Grissom
Office of Grants Management
National Center for Research Resources
6701 Democracy Boulevard, Room 1036
Bethesda, MD 20892
Telephone: (301) 435-0844
FAX: (301) 480-3777
Email: grissomi@mail.nih.gov

Ms. Joy Kearse
Grants Administration Branch
National Cancer Institute
6120 Executive Boulevard, Room 243
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Bethesda, MD 20892-7180
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Bethesda, MD 20892-8403
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FAX: (301) 594-6849
Email: edavis1@nida.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com/>. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

The title and number of this program announcement must be typed on line 2 of the face page of the application form and the YES box must be checked.

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at <http://grants.nih.gov/grants/dates.htm>. Application deadlines are also indicated in the PHS 398 application kit.

SPECIFIC INSTRUCTIONS FOR MODULAR BUDGET GRANT APPLICATIONS:

Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular budget grant format. The modular budget grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING \$500,000 OR MORE PER YEAR:

Applications requesting \$500,000 or more in direct costs for any year must include a cover letter identifying the NIH staff member within one of NIH institutes or centers who has agreed to accept assignment of the application.

Applicants requesting more than \$500,000 must carry out the following steps:

- 1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;
- 2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,

3) Identify, in a cover letter sent with the application, the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be mailed on or before the receipt dates described at <http://grants.nih.gov/grants/funding/submissionschedule.htm>. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an unfunded version of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. Appropriate scientific review groups convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- o Receive a written critique
- o Receive a second level review by the appropriate national advisory council or board

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to evaluate application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application.

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

SIGNIFICANCE: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

INNOVATION: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

INVESTIGATOR: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

ENVIRONMENT: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL REVIEW CONSIDERATIONS

Sharing Research Data.

Applicants requesting more than \$500,000 in direct costs in any year of the proposed research are expected to include a data sharing plan in their application. The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or priority score. Please refer to NOT-OD-03-032, <http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- o Scientific merit of the proposed project as determined by peer review
- o Availability of funds
- o Relevance to program priorities

REQUIRED FEDERAL CITATIONS

ANIMAL WELFARE PROTECTION: Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>), as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>), as applicable.

SHARING RESEARCH DATA: Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible. http://grants.nih.gov/grants/policy/data_sharing

Investigators should seek guidance from their institutions, on issues related to institutional policies, local IRB rules, as well as local, state and Federal laws and

regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.healthypeople.gov/>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-

Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

[Return to Volume Index](#)

[Return to NIH Guide Main Index](#)



Department of Health
and Human Services



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